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April 18, 2008

Via Electronic Transmission

Laurie A. Oberembt, Esq.
Department of Justice
Commercial Litigation Branch (Fraud)
Civil Division
Patrick Henry Building
601 D Street, NW - Room 9148
Washington, DC 20044

Re: *United States ex rel. Ven-A-Care of the Florida Keys v. Roxane Laboratories, Inc., et al*, Civil Action No. 07-10248-MEL

Dear Laurie:

I am writing this letter to address several outstanding issues with respect to the Government's damages disclosures, as well as its production of Medicaid claims data. In particular, the Government's damages disclosures to-date are plainly inadequate and fail to provide any meaningful information on the Government's theory of damages, much less any specific damage figures. As this issue has recently been the subject of correspondence between counsel for the Government and Abbott Laboratories, I attach March 5 and April 17, 2008 correspondence from Abbott counsel to the Government that outline the broad range of issues pertaining to the Government's inadequate damages disclosures, which equally apply to the present case. In the interest of brevity, I will not repeat the details outlined in those letters, but rather will highlight some of the key outstanding issues:

- The Government has yet to provide *any* detail regarding the methodology or assumptions pertaining to the so-called "alternative damages theory" identified in its Rule 26 disclosures. For instance, the Government has not articulated in any fashion its methodology for determining the Government's "but-for" price for the products at issue in this case;
- The Government has not provided any support for its so-called "tainted claims" theory, and, as Abbott counsel makes note, there is no legal or factual support for this theory;

KIRKLAND & ELLIS LLP

Laurie A. Oberembt, Esq.

April 18, 2008

Page 2

- The Government has not provided *any* estimates of the actual damage figures under its “alternative damage theory,” broken down by Medicare and Medicaid programs.

Abbott’s March 5, 2008 letter details the type of information that should have been provided to Roxane by this point in the case, and I incorporate that list by reference since it is equally applicable to the Roxane matter. (*See pp. 3-5*) The Government kept the Roxane complaint under seal for at least seven years, and thus had plenty of time to develop its damages theory. In addition, Roxane produced transactional data to the Government on all the NDCs at issue in December 2007, and produced much of this data to the Relator Ven-A-Care in the Texas litigation many years ago, as well as in the Florida litigation. Thus, to the extent that the Government is developing a theory based on actual sales prices to Roxane’s customers, the Government has had the data to make the necessary computations for quite some time. Alternatively, to the extent that the Government’s damages theory pertains to Roxane’s AMP data, the Government has also had that information for many years.

Although the Government has agreed to produce Medicaid claims data pertaining to the Roxane drugs at issue for all fifty states, it has only produced a very small subset of these claims in the six months since Roxane served its First Request for Production of Documents.

Specifically, Roxane appears to have received data from only five states. In addition, the Government has not provided a firm date (or even an estimate) of when it intends to produce complete Medicaid claims data. This is troubling because the fact discovery deadline in this case is only a few months away (August 29, 2008) and, as the Government knows, the review and analysis of claims data is a time-consuming and burdensome task. And, as Abbott’s April 17, 2008 letter documents, the productions of claims data to-date appear to be rife with errors, which also adds substantial delay to the process.

It is important to note that the Government’s articulation of a cognizable damages theory and its production of full and complete Medicaid claims data are not issues that can merely await expert discovery. To the contrary, the Government’s damages theory, and, in particular, its explanation of its “but-for” payment figures under both the Medicare and Medicaid programs, is properly the subject of fact discovery. For instance, Roxane is entitled to question pertinent HCFA/CMS personnel on the viability of the Government’s “but-for” hypotheses – but plainly cannot do so until the Government explains precisely what its damages theory is. Similarly, Roxane cannot effectively examine Medicaid personnel (or fiscal agents) with regard to their actual payment methodology without first receiving complete and accurate Medicaid claims data, and then having a reasonable opportunity to analyze the data. Thus, additional delay in the production of claims data severely prejudices Roxane’s ability to defend this case.

KIRKLAND & ELLIS LLP

Laurie A. Oberembt, Esq.
April 18, 2008
Page 3

Although Roxane has been extremely patient in awaiting supplemental disclosures as to the Government's damages theory, as well as complete production of claims data, the fact discovery cut-off in this case is fast approaching . As a result, Roxane respectfully requests that by May 1, 2008, the Government provide it with (1) supplemental damage disclosures and (2) a firm date for complete production of all claims data.

I look forward to your response.

Sincerely,

/s Eric Gortner

Eric T. Gortner

Enclosures

cc: Barbara H. Smith, Esq.
 Roslyn G. Pollack, Esq.
 Counsel for Abbott Laboratories
 Counsel for Dey